US008066768B2

(12) **United States Patent**
Werblin

(10) **Patent No.: US 8,066,768 B2**
(45) **Date of Patent: Nov. 29, 2011**

(54) **INTRAOCULAR LENS SYSTEM**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 398 days.

(21) Appl. No.: **11/698,875**

(22) Filed: **Jan. 29, 2007**

(65) **Prior Publication Data**

US 2008/0183289 A1 Jul. 31, 2008

(51) **Int. Cl.**
A61F 2/16 (2006.01)

(52) **U.S. Cl.** **623/6.34**; 623/6.4; 623/6.43

(58) **Field of Classification Search** 623/6.13, 623/6.34, 6.57, 6.32, 6.44
See application file for complete search history.

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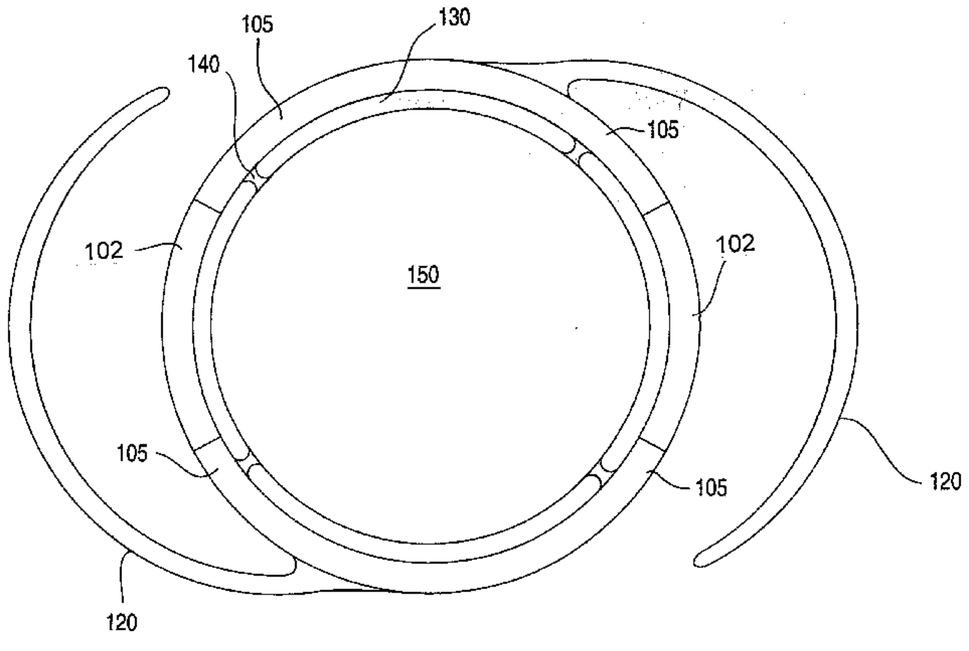
(57) **ABSTRACT**

A multi-component intraocular lens implanted in an optical system of a human eye includes one or more removable components, each component being foldable. One component acts as a base lens, including a flange with an aperture. Another component acts as a mid lens, including a tab which engages the aperture. A third component acts as a top lens, which engages the mid lens. Because the lens components are foldable, they may be inserted into the eye using an incision smaller than the diameter of the unfolded lens. The removable components may be used to correct various medical conditions of the eye, as well as to improve and enhance vision, and for cosmetic purposes.

22 Claims, 13 Drawing Sheets



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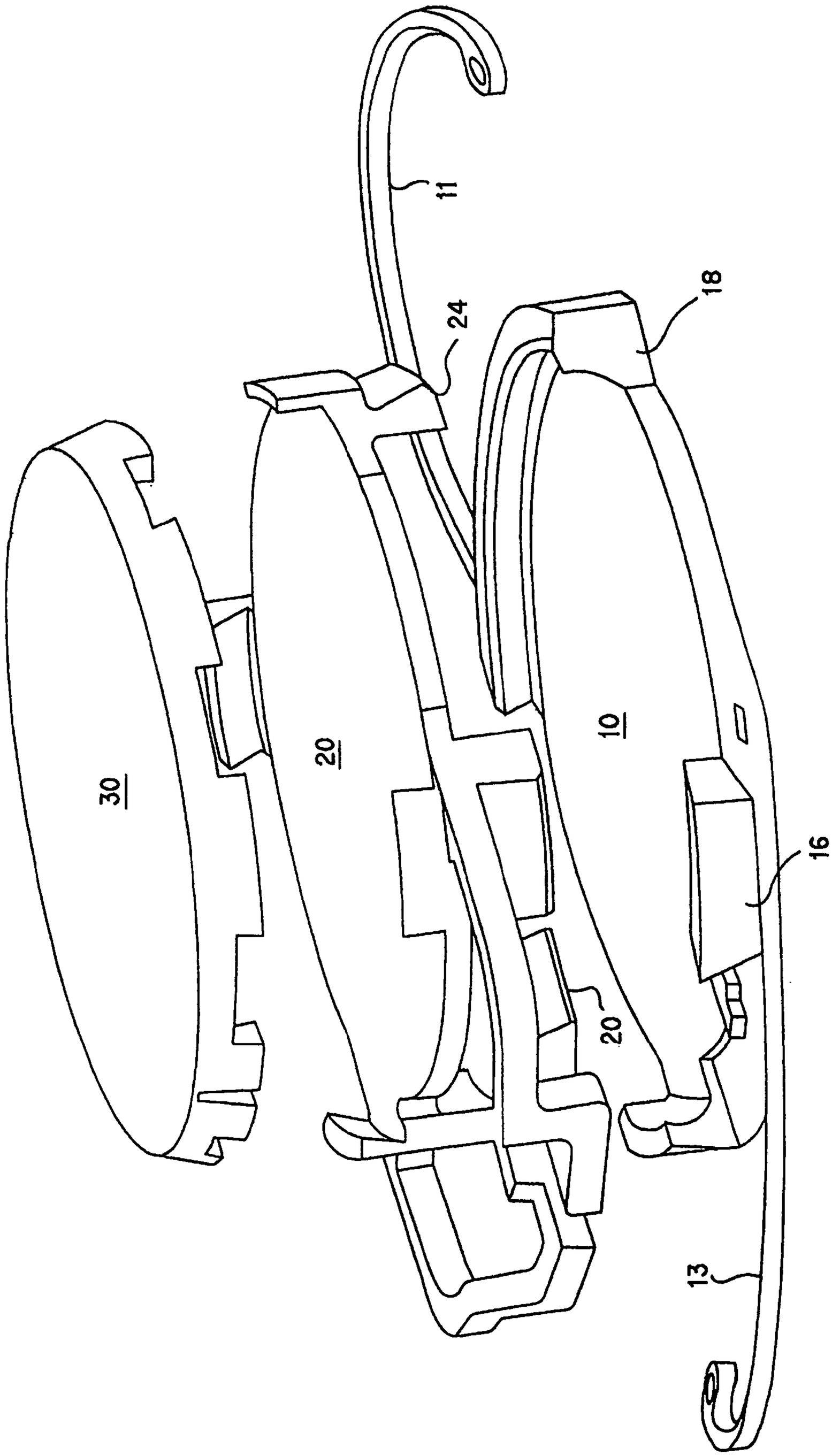

FIG. 1
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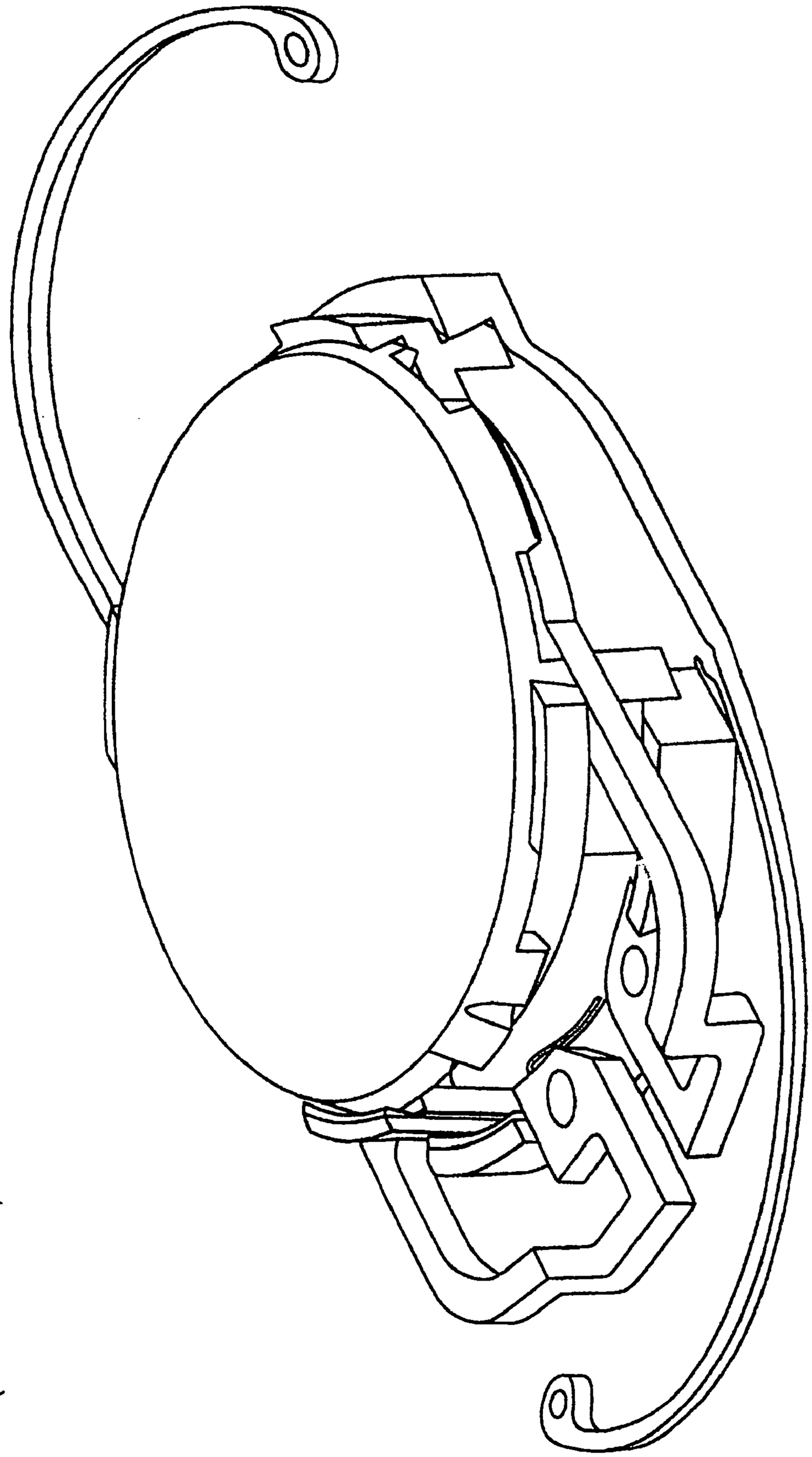

FIG.2
(RELATED ART)

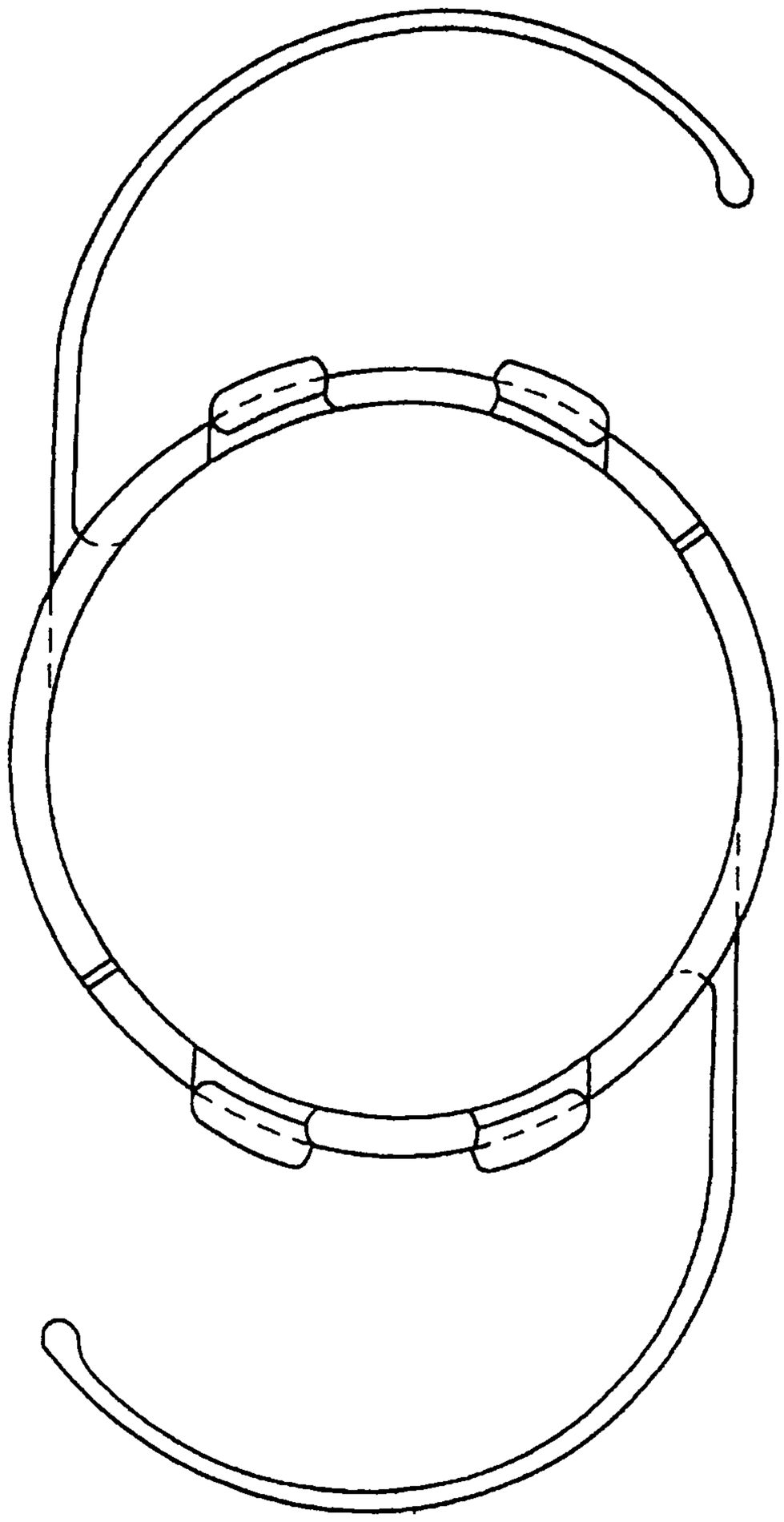

FIG.3A
(RELATED ART)

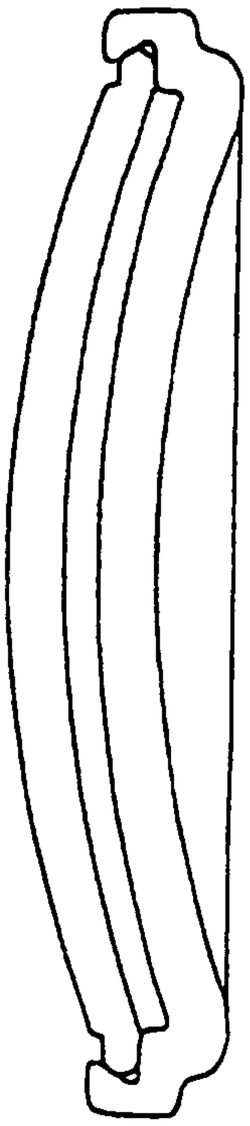

FIG.3B
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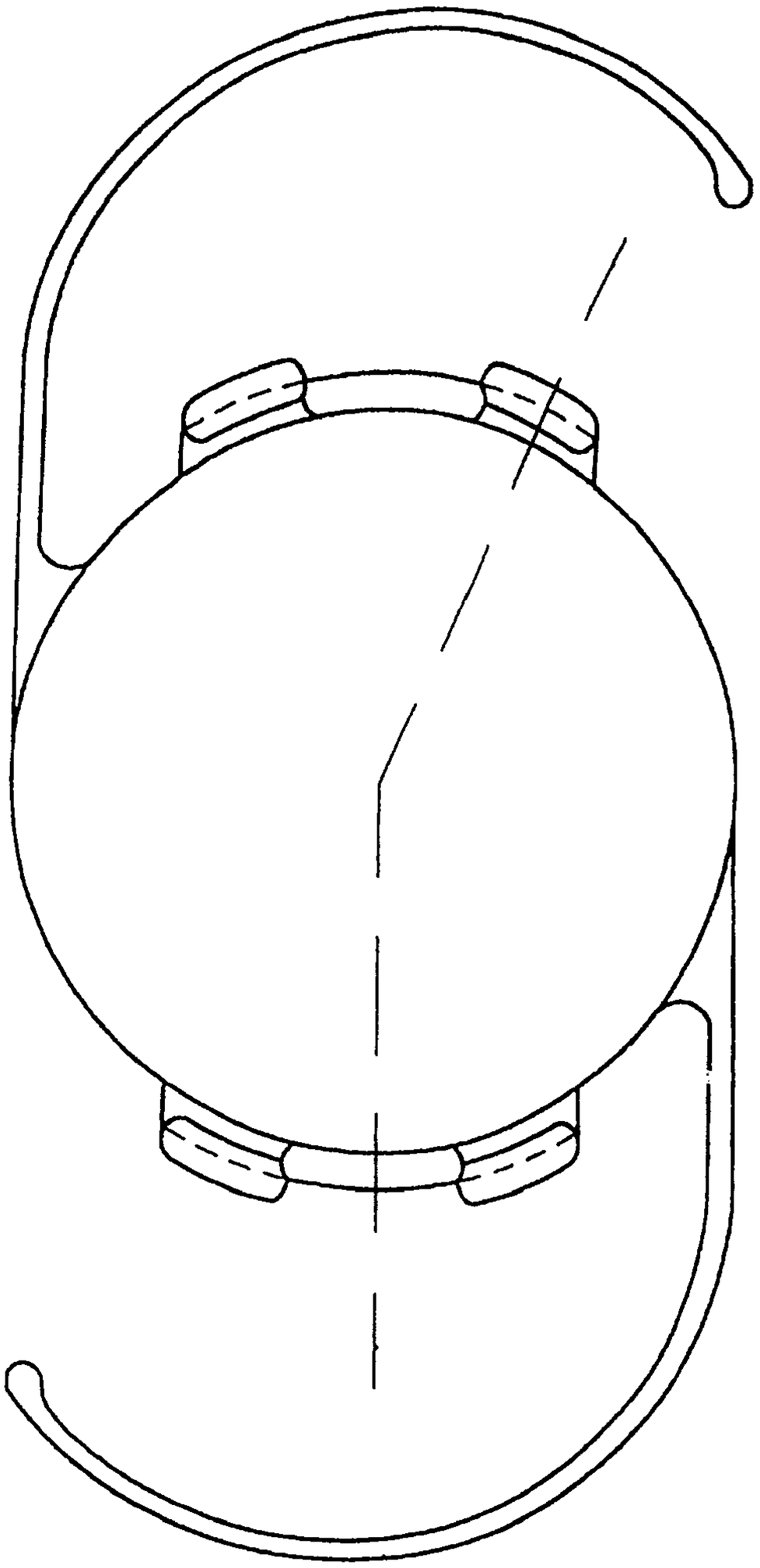


FIG.4A
(RELATED ART)

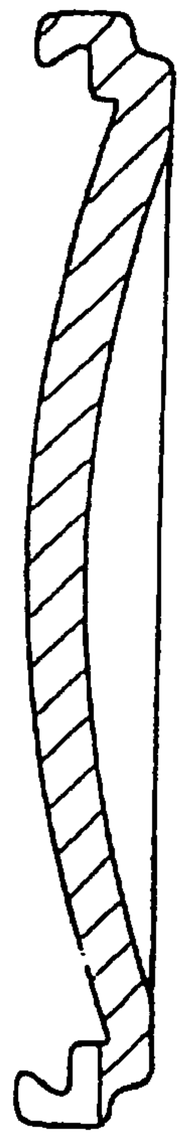


FIG.4B
(RELATED ART)

FIG.5A
(RELATED ART)

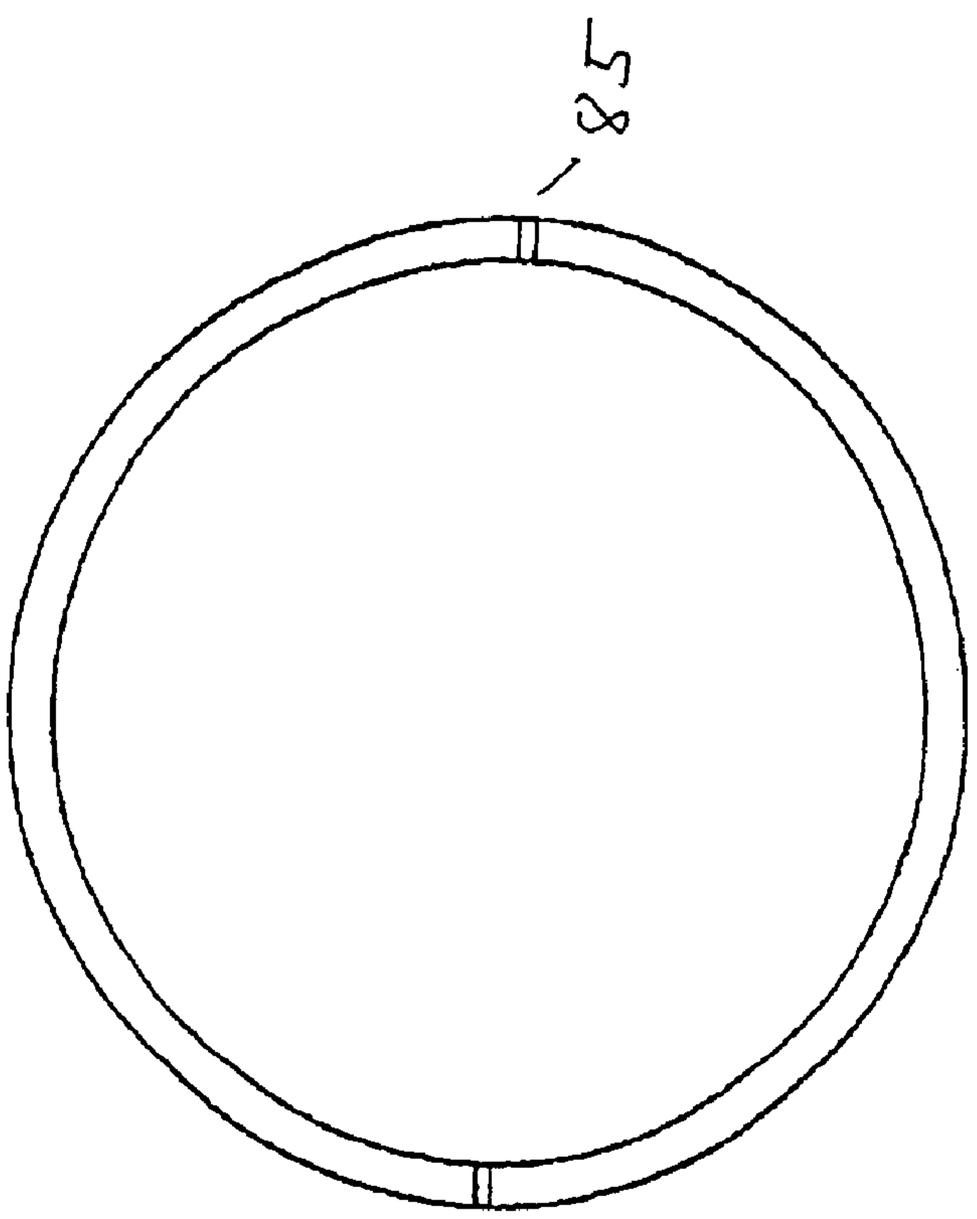


FIG.5B
(RELATED ART)

FIG.6
(RELATED ART)

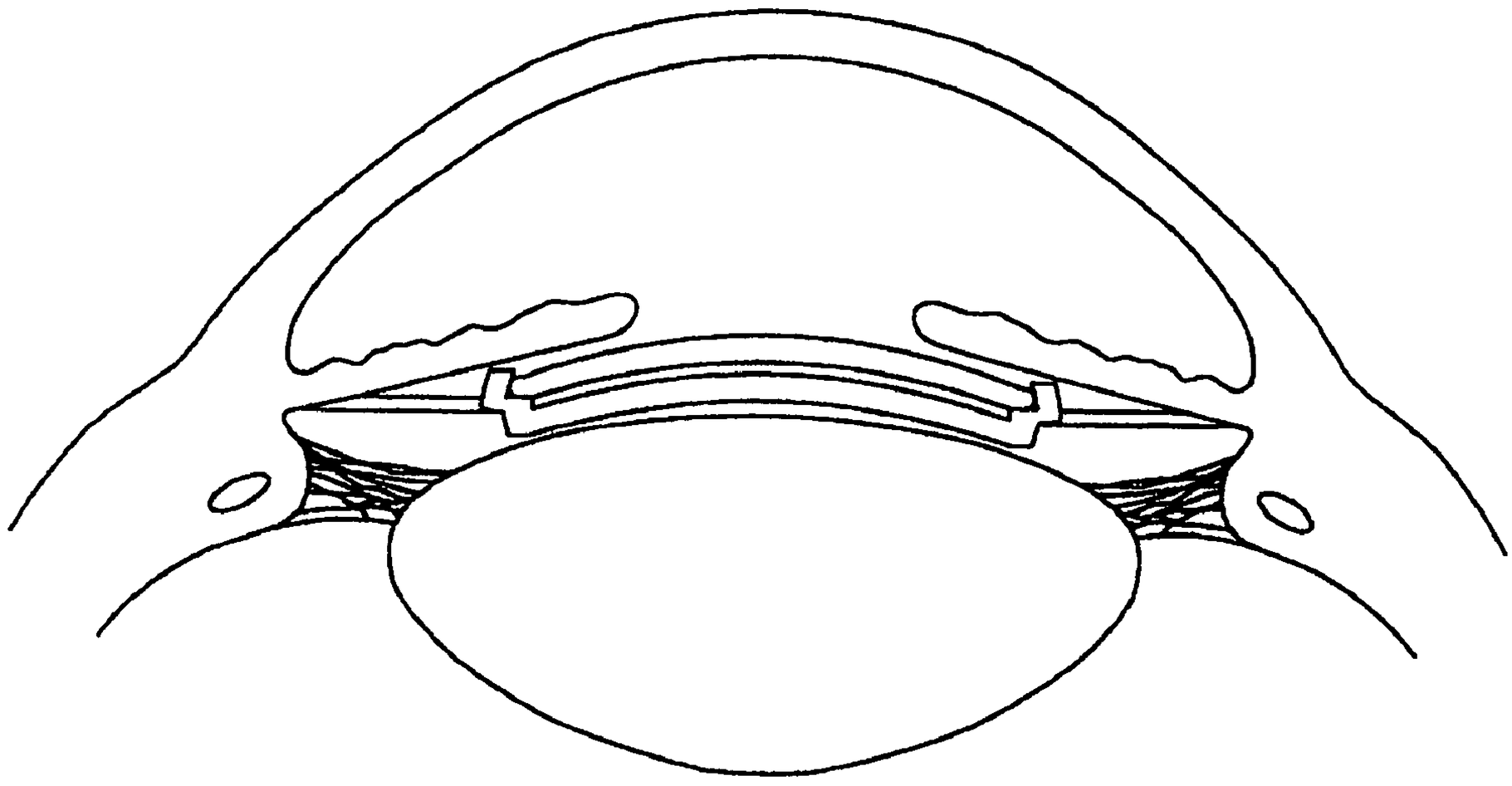


FIG.7
(RELATED ART)

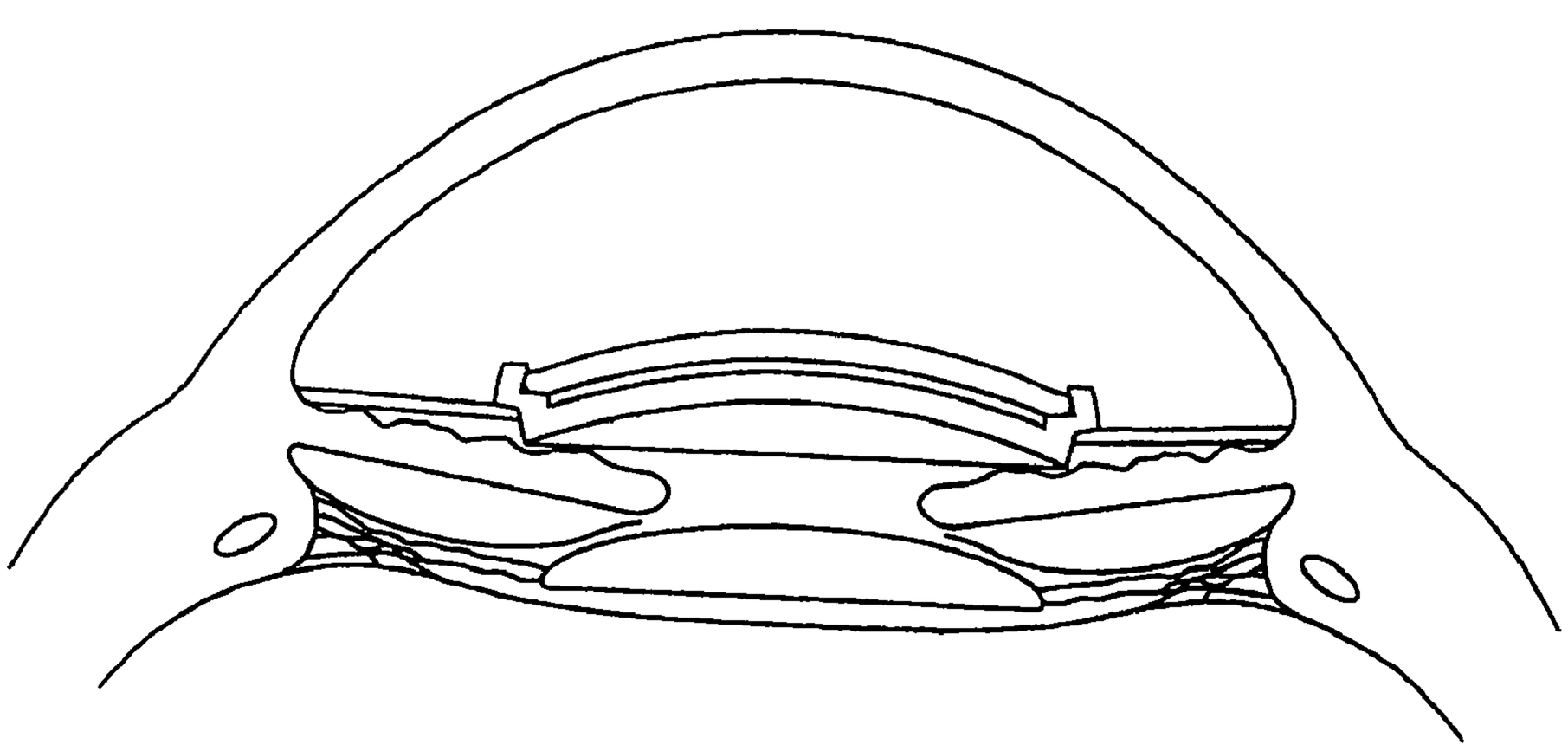


FIG.8
(RELATED ART)

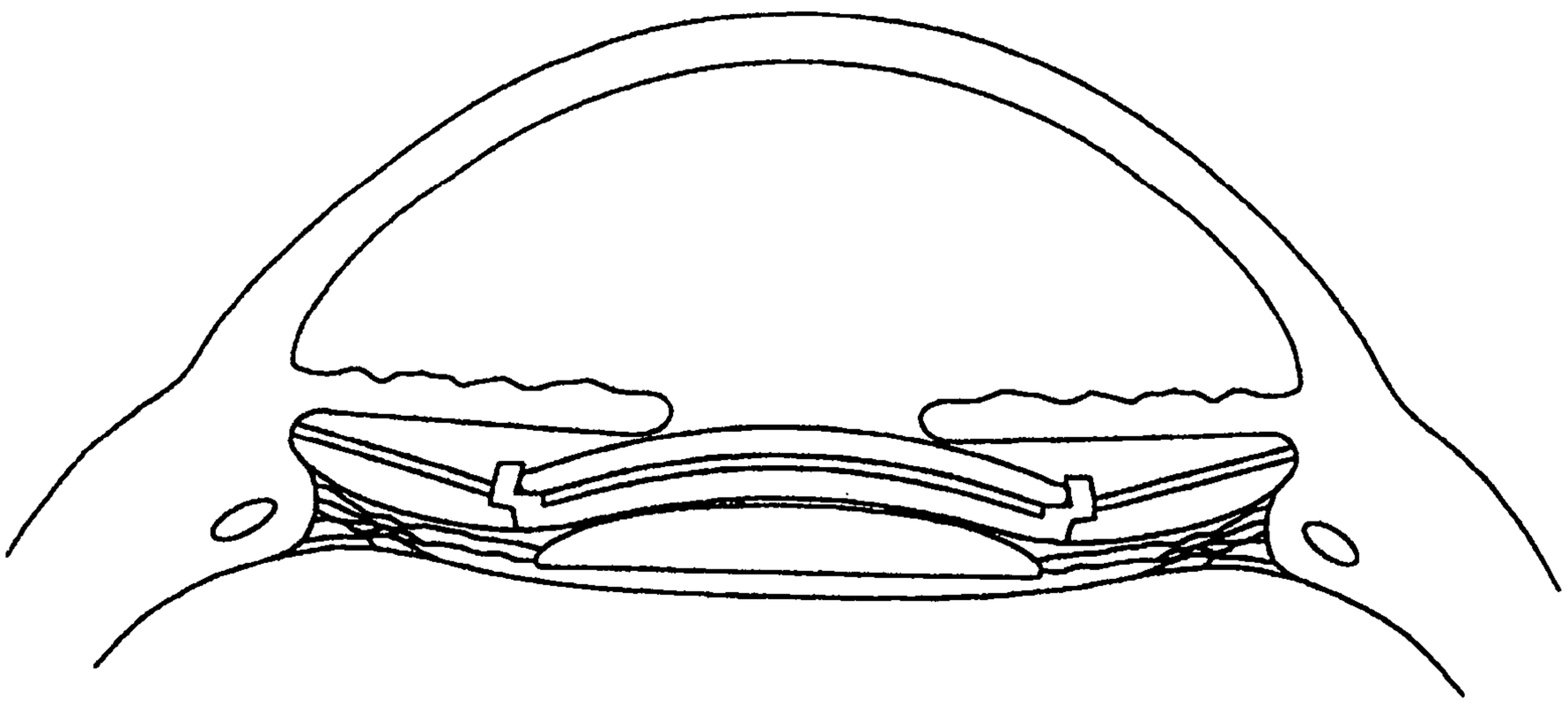


FIG.9
(RELATED ART)

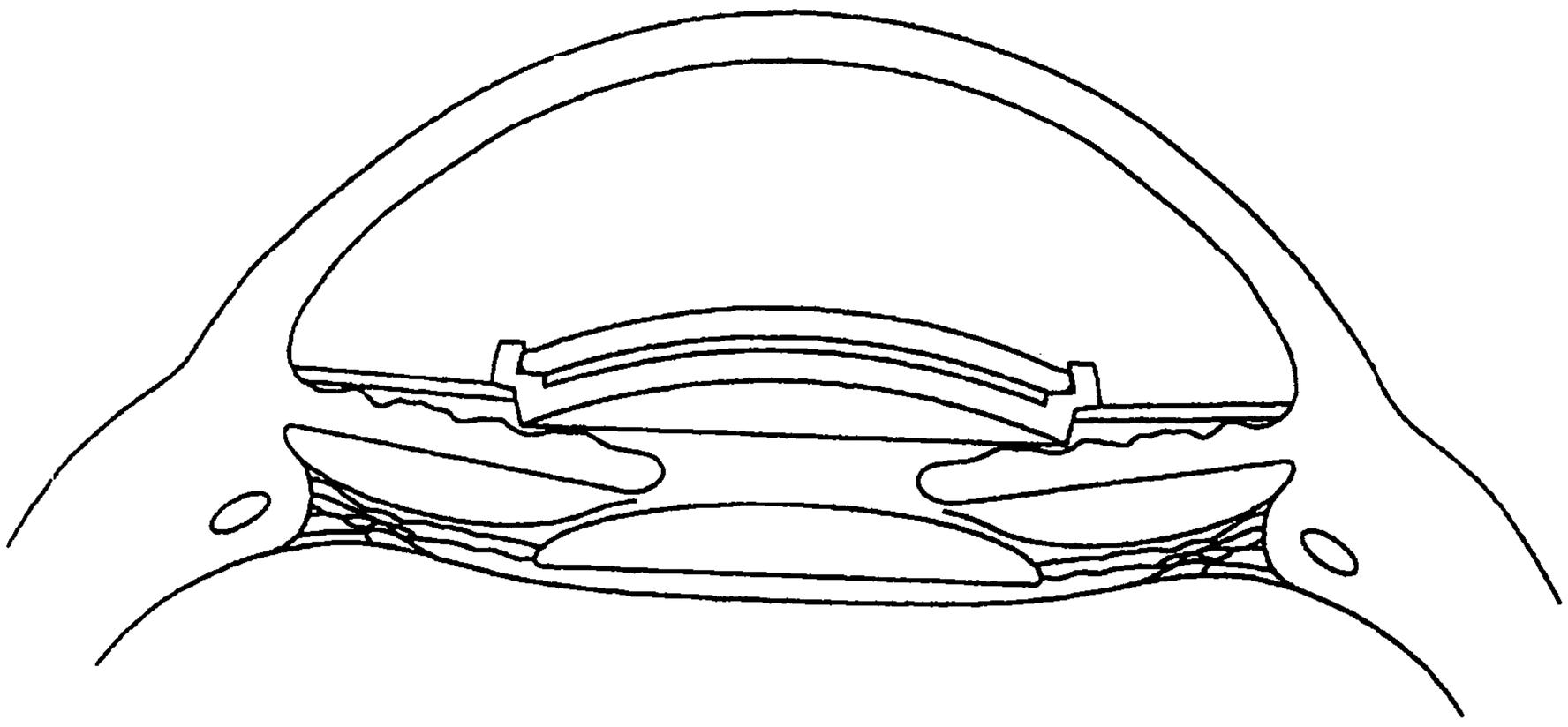


FIG. 10
(RELATED ART)

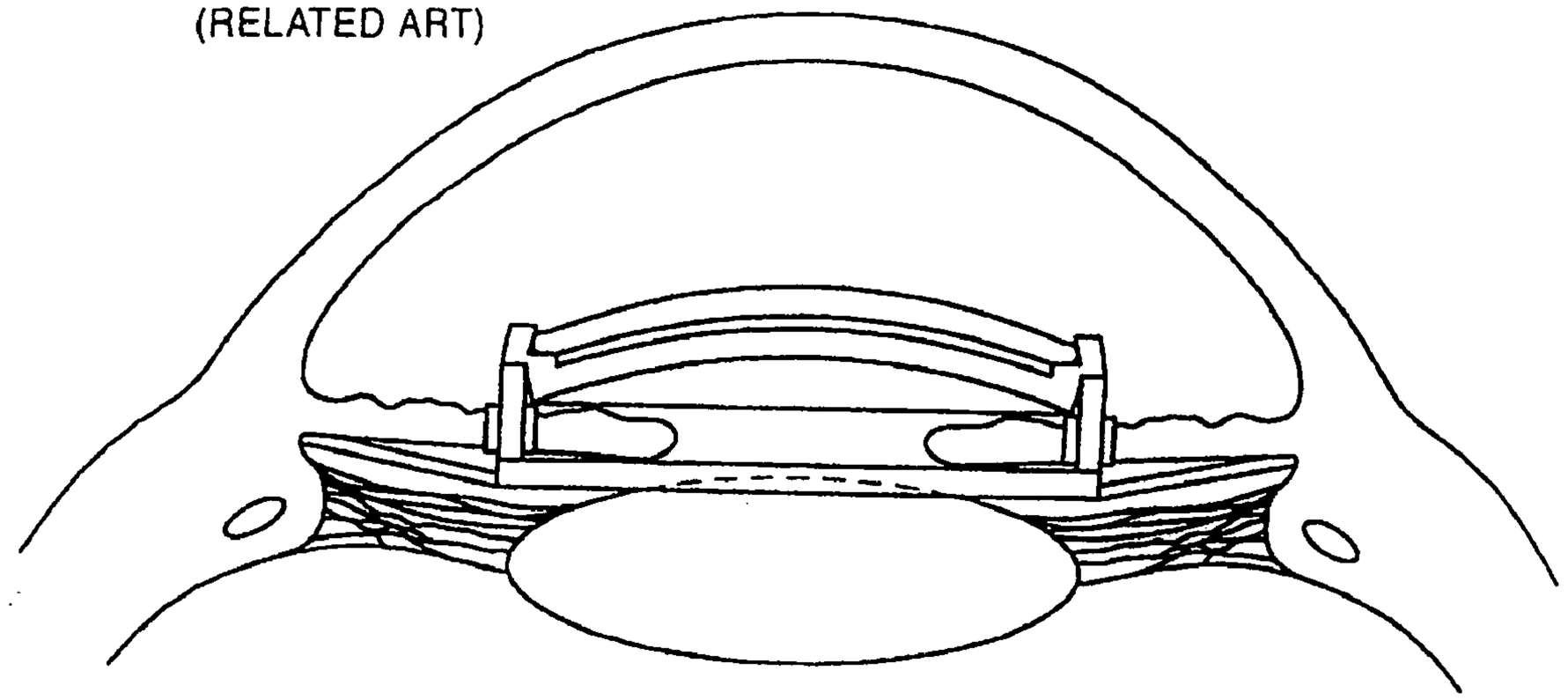
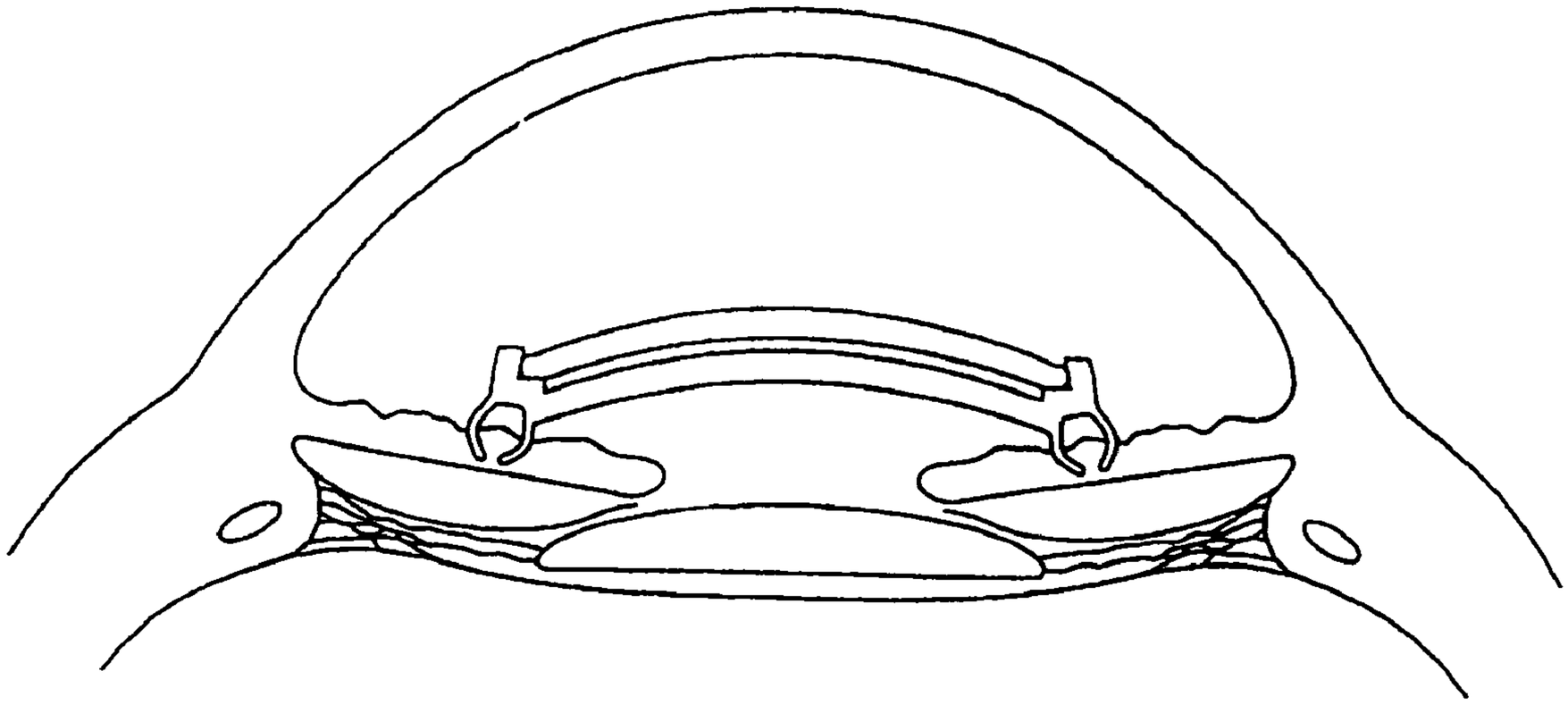


FIG. 11
(RELATED ART)



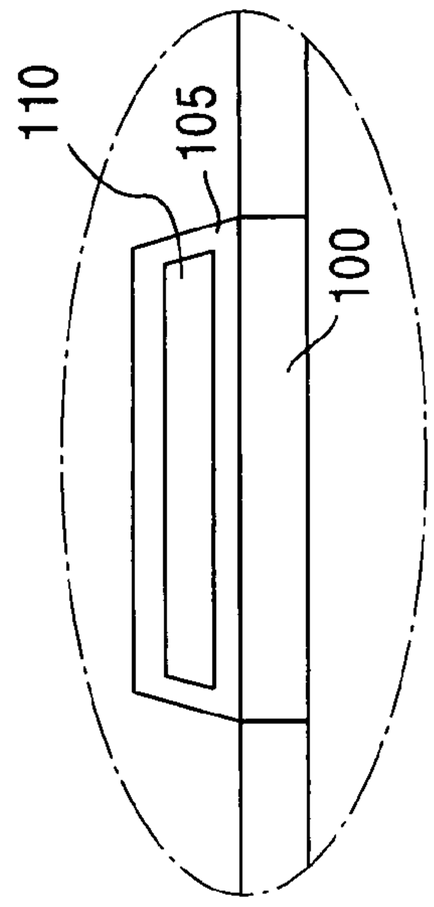


Fig.12B

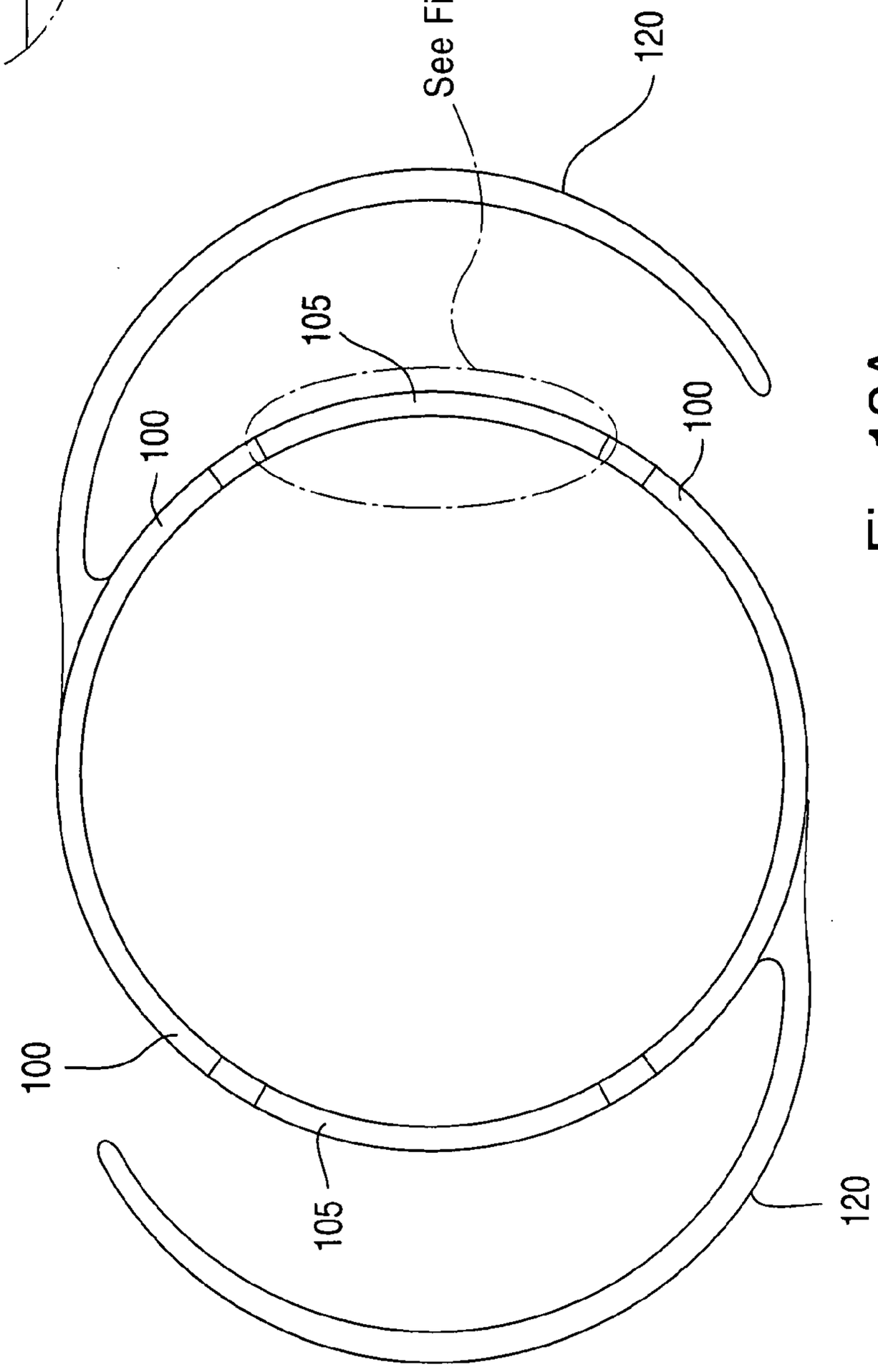


Fig.12A

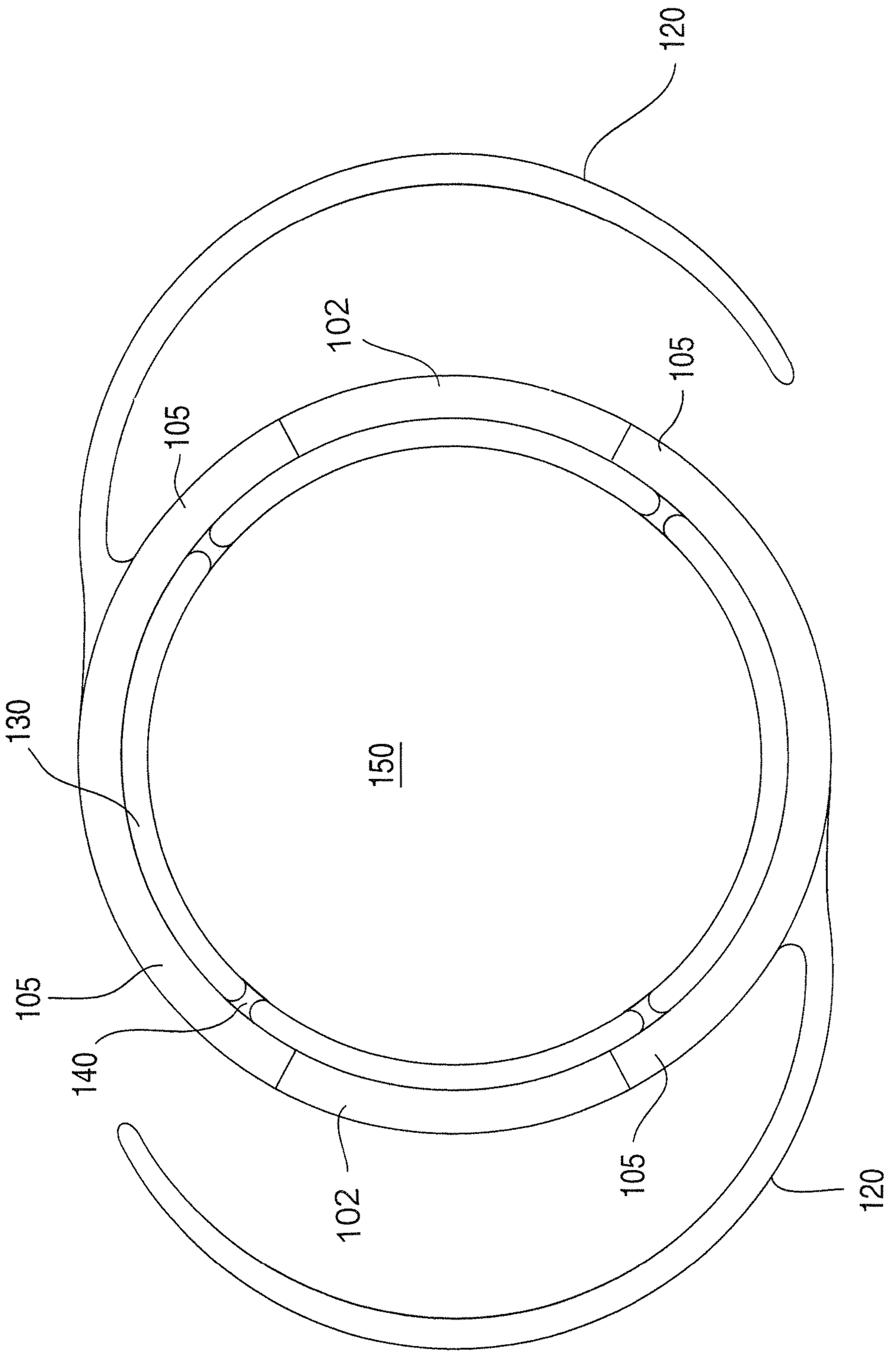


Fig.13

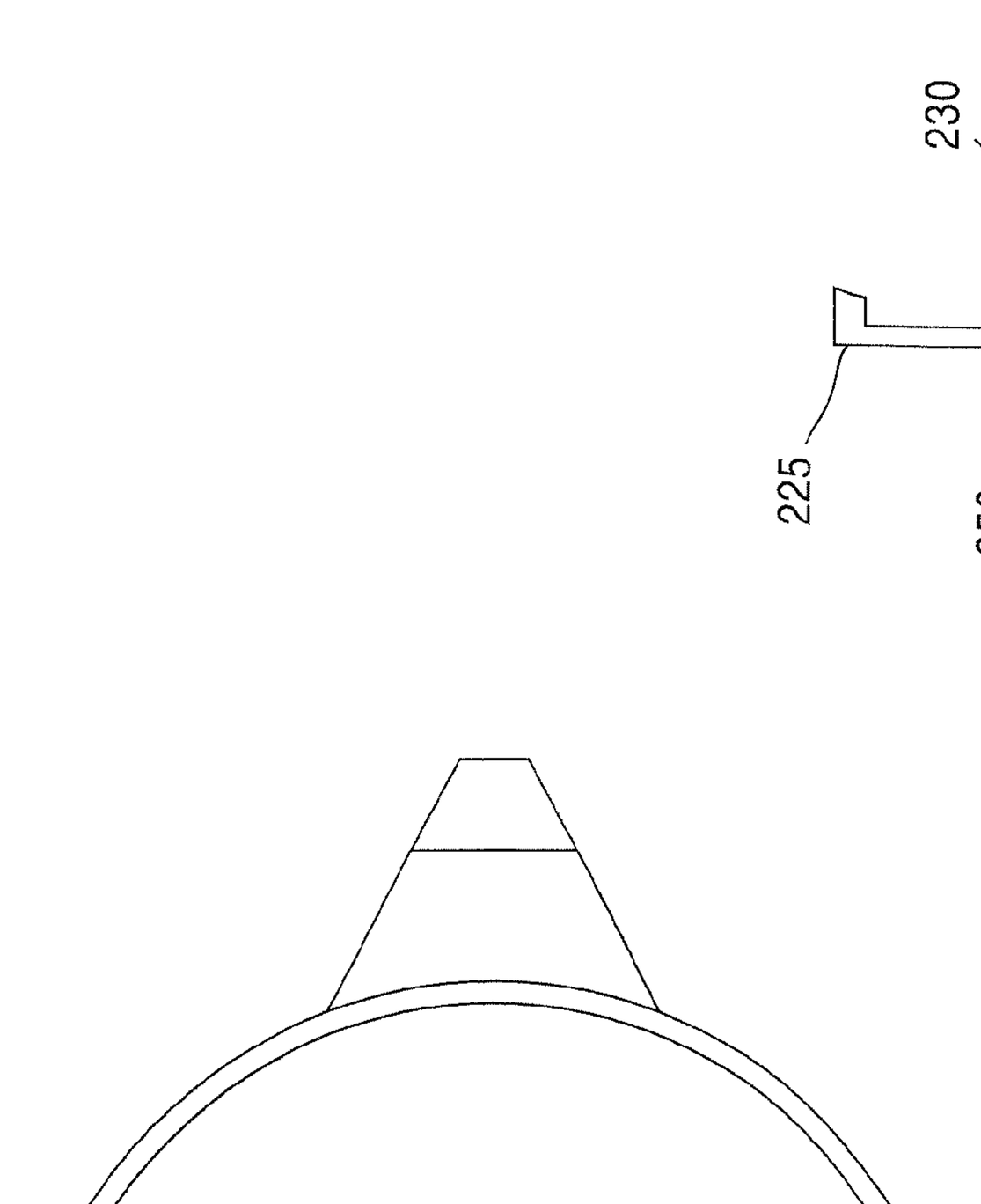


Fig. 14A

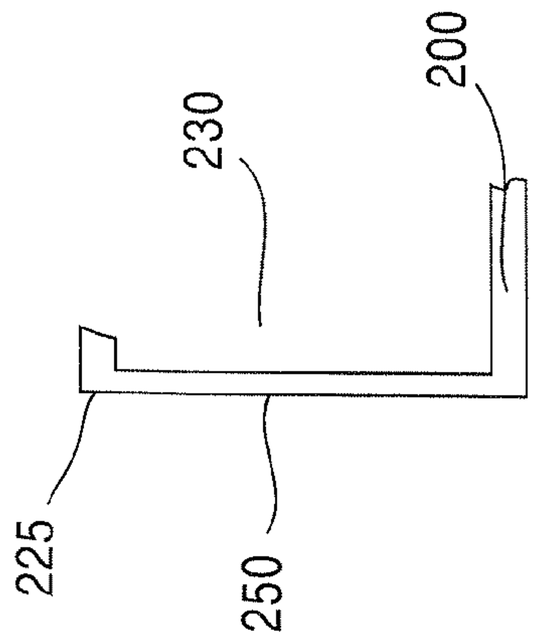


Fig. 14B

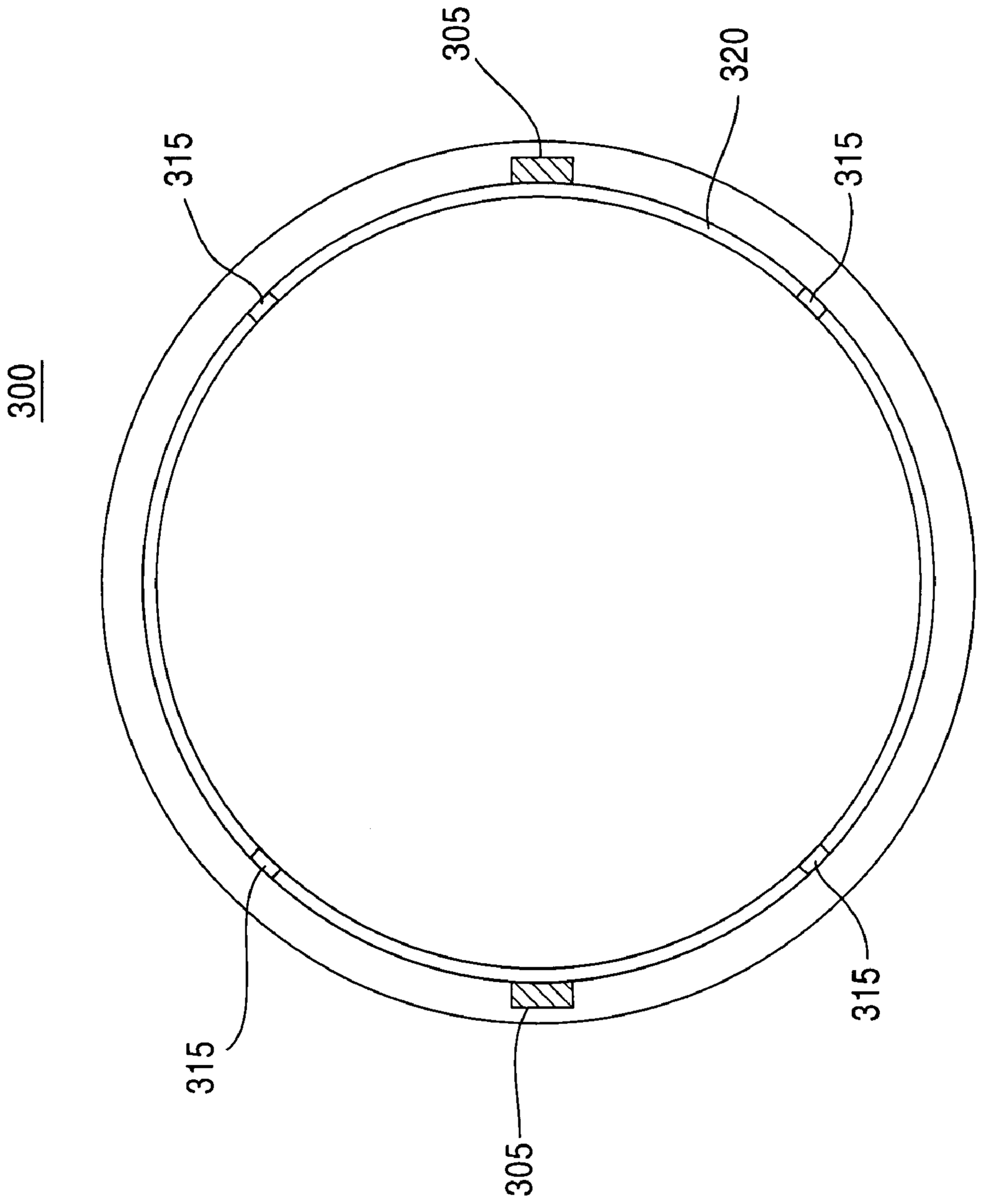


Fig.15

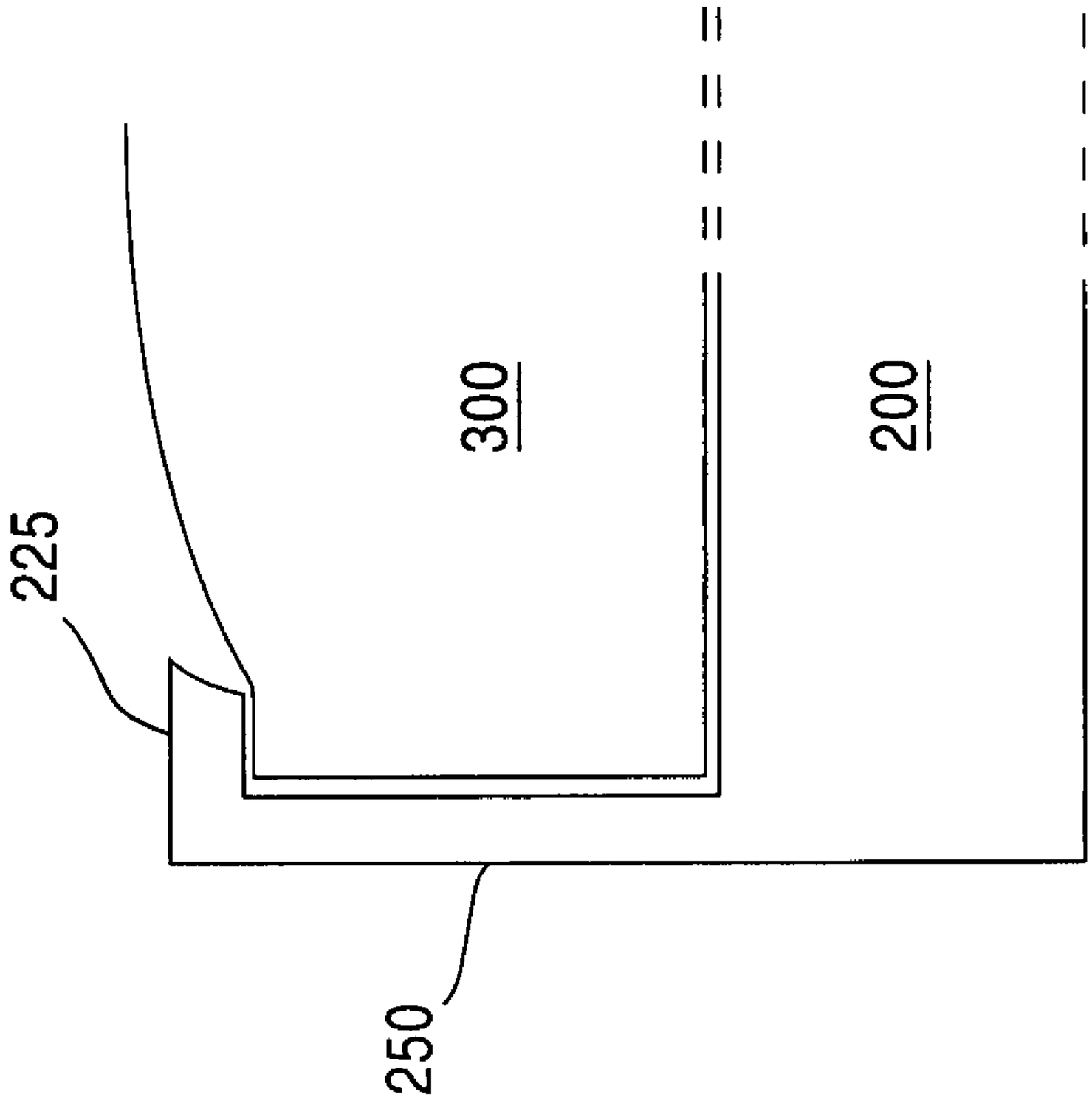


Fig.16

INTRAOCULAR LENS SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a method for correcting the optical system of an eye using an intraocular lens system. Particularly, this invention relates to a method of correcting focusing abnormalities and optical aberrations measured by wave front or similar technology to quantify optical aberrations in the optical system of the eye, using a laser, or other apparatus and/or methods of fabricating or modifying a lens, for the optical system of an eye having a foldable, interchangeable intraocular lens system provided therein.

2. Description of Related Art

The field of refractive surgery has evolved rapidly during the past few decades. Current procedures and methods used by refractive surgeons may not satisfy the total refractive needs of the patient. Particularly, the most commonly performed refractive surgical procedures, such as, for example, cataract extraction with intraocular lens implantation, in addition to the most recently popularized corneal refractive surgical procedures, such as eximer laser photoblation, exhibit limitations. One reason for the limitations is the lack of post-operative refractive accuracy. The lack of post-operative refractive accuracy renders the commonly known refractive surgical procedures uncompetitive with currently available non-surgical alternatives for patients, for example, glasses and contact lenses. Further, because refractive surgery requires local or general anesthesia and incisions into the eye, a need exists for decreasing the trauma resultant from the surgery.

Recently, a need has arisen for efficient treatment of presbyopia, or the diminished power of accommodation of the eye. Presbyopia is a condition which typically affects a large number of people as they age, with the severity of the condition varying depending on the person. Difficulties arise in treating presbyopia because typically once a person manifests symptoms of presbyopia, the symptoms worsen as the person ages. As a person's condition worsens, a different, usually more powerful, lens is required to correct the condition. Conventional techniques for replacing an intraocular lens each time the patient's vision deteriorated do not always present a practical or cost-effective approach. Recent developments in the field, of refractive surgery have made intraocular treatment of presbyopia a feasible course of treatment for those patients that desire or need improved vision, however a need exists for more precise techniques and devices for use in refractive intraocular surgery.

Patients suffering from eye trauma or other eye afflictions may have the iris or other portions of the eye distorted, destroyed, or discolored. Currently, such patients are typically prescribed cosmetic contact lenses. Cosmetic intraocular lens replacement is emerging as a viable alternative, however a need exists for more efficient intraocular lens replacement in order to minimize eye trauma and establish cosmetic intraocular lens replacement as a safe and effective alternative to cosmetic contact lenses and other nonsurgical treatments. As surgical techniques become more effective, safer, and less painful, patients may choose to have elective lens replacement surgery to change the color, structure, or shape of their eyes. By providing a minimally invasive method for lens replacement as described in an embodiment herein, the surgeon is able to limit the drawbacks of the procedure.

Current procedures and methods for refractive surgery require the performing surgeon to execute the procedure with

a high level of skill and experience. Currently, methods and procedures for carrying out refractive surgery involving intraocular lenses generally require direct visualization of the intraocular lens assembly within the eye. Such visualization, although not outside the scope of a surgeon skilled in the art, increases the degree of difficulty of the procedure, thus increasing the chance that a surgical error or other problem will arise in the surgical procedure, leading to unwanted complications. Thus, a need exists for intraocular lens assemblies and systems whose structures provide less complex methods of insertion into and extraction from the eye.

Currently, refractive cataract surgeons performing the most common refractive surgical procedure, i.e., routine cataract surgery, obtain refractive accuracies in a +/−0.75 to +/−1.00 diopter (D) range. However, the industry has established goals of obtaining refractive accuracies in the +/−0.25 D range. Therefore, there is a need in the industry to provide a more accurate alternative to the current procedure. Furthermore, analyses of current corneal refractive technologies indicate the presence of a significant amount of preexisting or naturally occurring post-operative, as well as preoperative, image distortion (optical aberration) or degradation, particularly under low light conditions, such as when driving at night.

Due to the practical limits of performing intraocular surgery, as well as the biological and physical behavior of the human eye during and after various types of intraocular surgery, predictability at the +/−0.25 D accuracy level with-a single surgical procedure is difficult to achieve as a practical matter. Furthermore, factors such as biometry errors, variable wound healing, and capsular contraction around the intraocular lenses contribute to decreasing the likelihood of achieving the desired refractive accuracy. Accordingly, practitioners in the industry have found that an adjustable intraocular lens (IOL), hereinafter referred to as the MC-IOL (multi-component) or C-IOL (compound), following lens extraction surgery provides a plurality of desirable options for refractive surgeons and patients.

An adjustable IOL allows fine tuning of the initial refractive result by exchanging at least one of the optical elements of the lens implant. As a result, accuracies in the +/−0.25 D range are readily attainable. Furthermore, patients are provided with an opportunity to exchange the "old" lens components with new and hopefully more accurate components. Such an objective is obtainable if the surgeon has an effective, efficient, and safe method of performing lens element exchanges. Additionally, months and/or years after the refractive surgical procedure, if the optical properties of the inserted IOL, for example, the multifocality, become problematic, the surgeon should have the ability to safely exchange the undesirable optical elements of the IOL to correct any optical aberrations that the patient will not or cannot tolerate.

In 1990, the inventor of this application developed a multi-component intraocular lens, hereinafter referred to as the MC-IOL (FIG. **1**), for use following clear lens or refractive cataract surgery, wherein the optical properties of the MC-IOL can be modified at any post-operative time. The base intraocular lens component of the MC-IOL is shown in FIG. **1**. The mid lens attaches to the top of the base lens and holds the third component of the MC-IOL, the top lens, in place.

The base intraocular lens **10** and the mid lens **20** each have securing flanges **16**, **18** and **20**, **24**, respectively, extending therefrom. The MC-IOL also comprises at least one top lens **30**, as illustrated in FIG. **1**. The top lens **30** is positioned on top of the mid lens **20**. See FIGS. **1-2**.

The MC-IOL also includes projections (or haptics) **11** and **13** which securely hold the MC-IOL in the tissue of the human eye. The above-described

structure permits the base intraocular lens **10** to form a platform upon which the mid lens **20** is placed, and to hold the top lens **30**. During routine cataract surgery, the MC-IOL replaces the crystalline lens of the human eye. Once a patient's eye has healed after such a surgery, the surgeon reenters the eye and replaces, if necessary, and more than once, the top lens **30** and the mid lens **20** to modify the optical characteristics of the eye until the desired levels for each optical characteristic are attained.

FIGS. **3**A-**3**B illustrate an assembled compound intraocular lens, hereinafter C-IOL, used with a preexisting lens within the human eye. The C-IOL has two components similar to the mid lens (FIGS. **4**A-**4**B) and the top lens (FIGS. **5**A-**5**B) components of the MC-IOL. FIG. **5** also illustrates the axis orientation mark **85** used in some embodiments of MC-IOL lenses, to aid in positioning and orienting the lens. The preexisting lens can be the crystalline lens of the eye with the C-IOL placed in the sulcus (FIG. **6**) or in the anterior chamber angle (FIG. **7**) of the eye's optical system. However, the C-IOL can also be used with a conventional IOL, as well as with an accommodating IOL, and mounted in the sulcus (FIG. **8**), in the anterior chamber angle (FIG. **9**), in the anterior chamber with posterior chamber fixation (FIG. **10**) or in the anterior chamber with iris fixation (FIG. **11**). Thus, a surgeon modifies the optical characteristics of the optical system of the eye by using the mid and top lenses in tandem with the preexisting conventional IOL implant or crystalline lens of the eye.

The C-IOL and MC-IOL provide numerous enhanced features. For example, the C-IOL and MC-IOL can each be structured as a monofocal or multifocal optical system, correct astigmatism, as well as comprise ultraviolet light-absorbing, tinted, or other such chemically treated materials.

It should be understood that there are various reasons why an adjustable MC-IOL or C-IOL is more desirable than a single component implant. In order to achieve all the permutations and combinations of the astigmatism, multifocality, and spherical correction needed to achieve emmetropia would take an inventory of over ten thousand lenses, whereas with the MC-IOL (multiple components) concept, an inventory of about one hundred components would be necessary. With anterior chamber lenses, progressive encapsulation or engulfment of the lens haptics by uveal tissue in the angle often occurs 1-2 years post-operatively. The engulfment typically makes the removal of the lenses and their haptics more difficult. Exchange of iris fixated anterior chamber lenses does not typically guarantee precise position or orientation. Posterior chamber lenses similarly cannot be removed because of posterior capsule fibrosis. Easy removal and exchangeability is critical for any customized emmetropic system, which can be provided by a specially designed multicomponent lens system.

Therefore, based on the above, a MC-IOL having three elements rather than one permits refractive customization and adjustability for all refractive errors, as well as for all patients, while using a minimal number of lens elements or parts and requiring little customization on the part of the manufacturer. Thus, it has become very important in the refractive surgery art to be able to individualize and/or customize surgery such that the surgeon can easily and safely, as well as accurately, modify the refractive power of an intraocular lens implant.

For example, U.S. Pat. No. 5,288,293 to O'Donnell, Jr. discloses a method of modifying a single IOL. O'Donnell suggests that the refractive power of a single IOL may be varied before implantation so that the changes can be made in situ by the ophthalmologist after determining the extent of correction required to improve the vision of the patient before the lens is made. However, the surgical implantation procedure itself may create additional optical aberrations which cannot be anticipated preoperatively and thus the primary lens implant cannot account for these optical aberrations.

As such, it may be argued that if a lens can be modified before being implanted, as suggested by O'Donnell, Jr., it should be possible to modify the implanted lens by removing the implanted lens, modifying the lens, and then reimplanting the modified lens into the optical system of the eye. However, the design of current intraocular lenses typically makes such a procedure difficult and impractical. Furthermore, after a period of time with normal healing, it becomes physically dangerous and/or nearly impossible to the patient to have the implanted lens removed once the eye tissue takes hold on the capsular fixation holes of the lens. Therefore, such an argument is not realistic, practical, or safe. A single component intraocular lens, which in general is not designed to be removed and with only two optical surfaces, cannot accurately allow for compensation of sphere, cylinder, cylindrical axis, and all forms of optical aberrations that may be discovered after the initial implantation. However, the MC-IOL typically will have four removable optical surfaces which can compensate for these optical properties.

The inventor of this application invented the previously discussed MC-IOL and C-IOL that are designed specifically to permit the easy exchange of optical elements at a post-operative period without risk to the human eye or to the patient, beyond the risk of ordinary intraocular surgery. The easy exchangeability of optical elements is critical because the actual surgery of implanting the lens in the first place, as well as variances in the manner in which the eye heals after implantation, potentially create distortions which may not stabilize for several months after the operation. Therefore, the ability to measure and to compensate for the distortion(s) optimally takes place several months after surgery and cannot typically be predicted prior thereto. Since the same surgical wound is used for both the primary and secondary operations, additional distortion due to wound healing would not be anticipated as a result of the second operation.

Furthermore, the ability to exchange optical elements of a multicomponent or compound intraocular lens can be economical compared to removing, modifying, and re-implanting a single component lens, as well as easier to perform.

The MC-IOL has four surfaces available for modification, two piano and two convex. Preferably, the modification is made only to the piano surfaces to avoid interfering with the convex side which may already be used for correction of astigmatism (cylinder) or used as a multifocal lens surface. The same preference applies to the CIOL, which has two surfaces available for modification, one piano and the other convex.

The inventor of this application also developed a system for correcting optical aberrations in the MC-IOL, as described, for example, in U.S. Pat. No. 6,413,276, for conducting measurements to determine any residual or new aberrations present in an operated eye after the biological healing parameters have stabilized, as well as to correct any errors in sphere, cylinder, or cylindrical axis, and for modifying one, two, or more existing lens elements within the implanted optical system based on the conducted measurements.

In conventional multi-component intraocular lens designs, the surgical procedure required to implant the intraocular lens components requires a high level of surgeon skill. For example, implantation of the removable component of the

lens requires the surgeon to directly visualize the placement of the lens in order to match the notches with the flanges. Further, removal of the removable lens component requires a special forceps tool for grabbing the base lens, and releasing the tabs holding the sandwich and cap lens together with the base lens (see, for example, the system described in U.S. Pat. No. 5,968,094).

Historically intraocular lens systems used a rigid one piece poly methyl methacrylate (PMMA) lens. The PMMA lens is approximately six millimeters in diameter. Because the PMMA lens is rigid, insertion of the PMMA intraocular lens generally requires a seven or eight millimeter incision to be inserted into the eye. In contrast, a flexible or foldable lens can be manipulated and compacted to a much smaller size. Once compacted, the multi-component intraocular lens can be delivered using a relatively smaller incision, for example, about three millimeters or less. By using a smaller incision, the patient reaps optical and practical benefits. From an optical standpoint, any time incisions are made to the cornea, the cornea loses some of its natural globularity due to imperfections caused by the incisions and the resultant trauma. The imperfections in the cornea lead to induced astigmatism, or optical aberrations caused by irregularities in the shape of the cornea. By minimizing the size of the corneal incision, a surgeon may also minimize the amount of induced astigmatism. Even though the three-component design simplifies the process of correcting induced astigmatism, minimizing the amount of induced astigmatism remains a primary goal for all intraocular surgeries.

As a practical matter, by making a smaller incision, the surgeon reduces the amount of actual trauma to the eye, thus reducing the occurrence of complications and decreasing the time for recovery. These advantages are further realized if the surgeon is able to perform the intraocular surgery using an incision small enough to heal without the use of stitches, wherein the incision is small enough to allow the eye's natural ocular pressure to hold the incision together during the healing process.

SUMMARY OF THE INVENTION

It is an aspect of this invention to overcome the above-described drawbacks of the related art.

In particular, it is an aspect of this invention to provide a multi-component intraocular lens system with components that are removable after placement in the eye. It is an additional aspect of the present invention to provide a multi-component intraocular lens system with foldable components in order to minimize trauma to the eye. Trauma is minimized by allowing the use of a delivery system for the foldable lens which requires an incision smaller than the unfolded diameter of the foldable lens.

It is a further aspect of this invention to provide a multi-component intrabcular lens system with components designed to simplify the surgical procedure for intraocular lens component insertion. An embodiment of the present invention includes a multi-component intraocular lens, wherein the base lens is attached with haptics, and the top and mid lenses are assembled outside the eye. The top and mid lenses may include projections designed to lock into place with flanges of the base lens. The intraocular lens system allows assembly without the use of special equipment or techniques for securing the top and mid lenses to the base lens. The intraocular lens system also does not require that the surgeon performing the operation be able to see or visualize the insertion of the top and mid lenses. Rather, in the present invention, the surgeon merely slides the folded mid/top lens assembly into the eye, unfolds the assembly in the eye, and slides the assembly across the base lens component until each projection aligns with a corresponding flange.

It is an aspect of the present invention to provide a modified multi-component intraocular lens implanted in an optical system of a human eye, including three or more removable components, with each component being foldable, and two of the removable components being connected to each other by a flange and slot.

It is a further aspect of the present invention to provide a multi-component intraocular lens for an eye, including a foldable base intraocular lens component, a foldable removable lens component, and a foldable mid intraocular lens component. The foldable removable lens component is attached to the foldable mid intraocular lens component by a notch along the circumference of the foldable removable lens component.

It is yet another aspect of the present invention to provide a system for the administration of pharmacological agents through an intraocular lens system capable of the time-delayed release of medicine into the eye over a predetermined, and/or adjustable period of time.

The use of an adjustable intraocular lens allows adjustment or exchange of optical elements, both spherical and cylindrical, independent of any additional wound healing or significant calculation error to fine-tune, reverse, or replace any of the original optical features.

BRIEF DESCRIPTION OF THE FIGURES

In the drawings:

FIG. **1** is a plan view of the base, mid, and top lens components of a currently known multi-component intraocular rigid lens;

FIG. **2** is an exploded side view of the assembled base, top, and mid lenses of the currently known multi-component intraocular rigid lens shown in FIG. **1**;

FIGS. **3**A-**3**B are exploded views of a two component compound intraocular lens;

FIGS. **4**A-**4**B are top and side views, respectively, of a type of compound intraocular lens-top lens component;

FIGS. **5**A-**5**B are top and side views, respectively, of a type of compound intraocular lens-top lens component;

FIG. **6** is a side view of a compound intraocular lens implanted within a human eye ciliary sulcus;

FIG. **7** is a side view of another compound intraocular lens implanted within a human eye using the anterior chamber angle as support;

FIG. **8** is a side view of a sulcus mounted compound intraocular lens implanted within a human eye with a previously implanted single component conventional intraocular lens mounted in the capsular bag;

FIG. **9** is a side view of an anterior chamber mounted compound intraocular lens implanted within a human eye with a previously implanted single component conventional intraocular lens mounted in the capsular bag;

FIG. **10** is a side view of an anterior chamber mounted compound intraocular lens on a support secured in the posterior chamber and is implanted within a human eye with a previously implanted single component conventional intraocular lens mounted in the capsular bag;

FIG. **11** is a side view of an iris fixated compound intraocular lens in the anterior chamber that is implanted within a human eye with a previously implanted single component conventional intraocular lens mounted in the capsular bag;

FIG. **12** is a top view, with an enlarged side view cutaway, of the base component of a foldable multi-component intraocular lens according to an embodiment of the present invention;

FIG. **13** is a top view of the base component of a foldable multi-component intraocular lens according to another embodiment of the present invention;

FIGS. **14**A and **14**B are an exploded top view and an exploded side view, respectively, of the mid lens replaceable component of a foldable multi-component intraocular lens according to an embodiment of the present invention;

FIG. **15** is an exploded top view of the top lens component of a foldable multi-component intraocular lens according to an embodiment of the present invention; and

FIG. **16** is a side view of the inventive assembly when the top lens is inserted into the mid lens according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **12** shows a top or plan view of the intraocular foldable base lens **100** in a preferred embodiment of the present invention. The base lens **100** is similar to the MC-IOL base lens illustrated in FIG. **3**. The base lens **100** is preferably manufactured from acrylic or silicone materials, but the base lens **100** can be manufactured from any suitable foldable material. The base lens **100** has a diameter ranging from 1.00 to 8.00 millimeters, but preferably is between 5.50 and 6.50 millimeters, and has an optical aperture ranging from 3.0 millimeters to 7.0 millimeters, with a preferable optical aperture of 5.5 millimeters.

As mentioned above, the base lens **100** has a diameter ranging from 1.00 to 8.00 millimeters, and is preferably composed of foldable material. Accordingly, the insertion of the base lens **100** into the eye requires an incision therein which is less than half as large as the diameter of the base lens **100**.

The base lens **100** attaches to the eye by at least one haptic **120**. In FIG. **12**, the base lens **100** is secured to the eye by at least one, but preferably two haptics **120**, however, this is merely one embodiment of the present invention, and other embodiments may use one or more haptics **120** to secure the base lens **100** to the eye.

The haptics **120** illustrated in FIG. **12** have a span ranging from 5.0 millimeters to 15.0 millimeters. In a system where the base lens **100** has two haptics extending outward, the two haptics each have a preferable span of 12.0 to 13.0 millimeters. The preferable length of the haptics **120** depends on the number of haptics extending from the base lens **100**. Each haptic **120** extends outward from the base lens **100**, and is tilted from between 10 to 20 degrees, in either direction, relative to a plane taken across the base lens, preferably having a 15 degree positive tilt.

The base lens **100** includes one or more flanges **105** disposed on and extending outwardly away from the body of the base lens **100**, preferably forming a perpendicular angle with the plane of the base lens, however the flanges **105** could extend outward from the body of the base lens at any angle from 45 degrees to 135 degrees. In a preferred embodiment, such as the embodiment illustrated in FIG. **12**, two flanges **105** are disposed on either side of the base lens **100**. However, the invention is not limited to this embodiment, as more flanges **105** may be disposed in various locations around the base lens **100**.

Each flange **105** has a slot **110** designed or configured to receive or accept an assembly of a top lens **300** and a mid lens **200** therein, which will be described in more detail herein. The slot **110** illustrated in FIG. **12** is in the shape of a parallelogram, however other shaped slots, such as elliptical, oval, trapezoidal, rounded rectangular, or any other known geometric shape are considered to be within the scope and pervue of the present invention.

The base lens incorporated into another embodiment of the present invention is illustrated in FIG. **13**. The base lens **102** is similar to the base lens **100**, except for a groove **130** defined in the base lens **100** and extending along the entire outer periphery of the base lens **102**, and four attachment points **140**, which serve to attach the optical region **150** to the base lens **102**. Although four attachment points **140** are illustrated here, embodiments with more attachment points or fewer attachment points are also considered to be within the scope and pervue of the invention. In all other aspects, the base lens **102** is the same as the base lens **100** illustrated in FIG. **12**.

In an embodiment of the present invention, the base lens **100** is infused with chromophores, which absorb light in a portion of the light spectrum. For example, the base lens could be infused with chromophores to absorb light from the ultraviolet wavelength portion of the light spectrum, typically between 380 and 389 nm. By absorbing light in the ultraviolet wavelength portion of the spectrum, the intraocular lens system reduces eye glare, enhances vision capabilities, and helps protect the eye from potentially harmful ultraviolet rays. Although ultraviolet light is exemplified here, other color chromophores, which are used to block other wavelengths of light, are also considered within the scope and pervue of the invention.

The foldable MC-IOL includes two or more additional refractive components, including an assembly of the top lens **300** and the mid lens **200**, described more fully herein. One embodiment of the mid lens **200**, hereinafter interchangeably referred to as the "middle" lens, the "cap" lens, or the "removable component" lens, is illustrated in FIGS. **14**A and **14**B. The mid lens **200** allows spherical adjustments from −4.00 D to +4.00 D in 0.25 D increments. In an embodiment of the present invention, the top lens **300** carries the astigmatic correction, which can range, for example, from 0.00 D to 5.00 D cylinder in 0.25 D increments and has an orientation projection **305**. The present values are presented merely for illustrative purposes, and other possible ranges for the cylinder at various sphere values are considered to be within the scope and pervue of the invention.

Like the base lens **100**, the top lens **300** may be constructed from acrylic, silicone, or any other material suitable for manufacturing a foldable intraocular lens. The top lens **300** has a central thickness ranging from 0.1 millimeters to 0.4 millimeters, and a diameter ranging from 1.50 to 8.50 millimeters, but preferably is between 5.50 and 7.00 millimeters. The top lens **300** features an optical aperture ranging from 3.0 millimeters to 7.0 millimeters, with a preferable optical aperture of 5.5 millimeters.

The mid lens **200** and/or the top lens **300** may serve multiple purposes depending on the specific embodiment and the specific nature of the problem to be solved. For example, the top lens **300** and/or the mid lens **200** may correct myopia, presbyopia, or astigmatism. The top lens **300** and/or the mid lens **200** may also be used to correct cosmetic defects in the eye. The top lens **300** and/or the mid lens **200** may also be tinted to protect the eye from ultraviolet rays, or blue light, or to reduce glare, or to change the color of the eye for cosmetic or other purposes. The top lens **300** and/or the mid lens **200**, like the base lens **100**, may also be constructed in a manner which allows the top lens **300** and/or the mid lens **200** to

absorb light in the ultraviolet wavelength portion of the light spectrum, for the purpose of achieving the same goals as mentioned above.

In an embodiment of the present invention, the top lens **300** and/or the mid lens **200** may be designed to change the light-gathering aspects of the eye to improve night vision. A lens with these characteristics has potential use for military applications, such as low light or telescopic use, or for underground workers, or in any other application where the patient desires reversibly enhanced night vision, or vision enhancement in a specific area of the spectrum. For example, athletes such as baseball players may desire amber-tinted lenses to improve their ability to perform the tasks critical to their sport, such as seeing the ball. Lenses designed for this purpose could be removed when the patient no longer desires the enhanced vision characteristic, for example when the military application is finished, or the athlete's season or career ends.

In another embodiment of the present invention, the top lens **300** and/or the mid lens **200** may be used to deliver pharmacological compounds, such as medicines, into the eye. The top lens **300** and/or the mid lens **200** in this embodiment feature a system for delivering a compound into the eye over a predetermined period of time. At the end of the predetermined time period, the surgeon removes the top lens **300** and/or the mid lens **200**, and replaces the top lens **300** and/or the mid lens **200** with a new lens for delivering a compound into the eye, if needed. In this way, the patient may conveniently receive delivery of a compound directly into the inner portions of the eye, while minimizing the risk to the patient, and simplifying the delivery of the compound. Because this treatment does not require recurring action by the patient, the treatment avoids the problem of patient non-compliance, which is critically important to the treatment of chronic eye disorders, such as glaucoma, diabetes, and macular degeneration.

FIG. **14**A illustrates a top view of the mid lens **200** of an embodiment of the present invention. The mid lens **200** includes one or more projections **210** extending horizontally from the body of the mid lens **200**, preferably in the plane parallel to the edge of the mid lens **200**, but optionally at any angle from 150 to 180 degrees in either direction. Each projection **210** may extend outward from the lens ranging from 0.5 to 5.0 millimeters from the outer edge of the mid lens **200**. Each projection **210** may also have varying lengths depending on the shape and number of projections. The projections are illustrated in FIG. **14**A as trapezoidal, but any shape which would accomplish the stated purpose of fitting into slot **110** of the flange **105** extending from the base lens **100**, for example, rectangular, triangular, half-oval, notched, ridged, serrated, or any other suitable geometric shape, is considered to be within the scope and pervue of the present invention. Additionally, any shape, indentation, marking, notching, or surface treatment of the flange **105**, including, for example, ribbing, roughening, adding bumps, notches, and indentations, are considered to be within the scope and prevue of the present invention. Likewise, the use of any adhesive material on the flange, for example, glues, Velcros, cements, resins, pastes, or any other adherent, is also considered to be within the scope and pervue of the present invention.

The mid lens **200** also comprises a side portion **250** which extends upward, and terminates at a lip **225**, as illustrated in FIG. **14**B. The side portion **250** and lip **225** extend along the outer circumference of the mid lens **200**, thereby defining a notch **230**. Although the lip **225** is illustrated in FIG. **14**B as having a relatively squared off end, the lip **225** may be configured to any suitable shape which does not prevent the formation of the notch **230**, such as, for example, a rounded end, an angled end, or a pointed end. Further, although not illustrated in FIG. **14**B, the lip **225** may also optionally be surface treated to have at least one of bumps, ridges, bevels, serrated teeth, gouges, notches, impressions, recesses, or other such surface treatments that are suitable for use in a notch. Additionally, although the notch **230** is illustrated as substantially defining a right angle between the side portion **250** and the lip **225**, the angle formed between the notch **230** and the lip **225** may range from 45 degrees to 135 degrees.

Prior to insertion into the eye, the top lens **300** (described further herein with respect to FIG. **15**) engages the notch **225**, such that a seal is formed between the notch **225** and the top lens **300**, and which holds the mid lens **200** and the top lens **300** together as a single assembly. The top lens **300** includes a groove **320** defined in a surface of the top lens **300**, and extends along the circumference of the outer periphery of the top lens **300**. The groove **320** extends along the circumference of the top lens **300**, except for the location of the compression slots **315**, as shown in FIG. **15**. Although four compression slots are illustrated here, embodiments with more compression slots or fewer compression slots are also considered to be within the scope and pervue of the invention. Groove **320** and a series of compression slots **315** allow easier fitting of the top lens **300** into the mid lens **200**. In other embodiments, the groove **320** could be replaced with other slots or channels defined in the periphery of the lens, and the invention should not be considered to be limited to this specific embodiment.

The top lens **300** also includes one or more end notches **305**. In FIG. **15**, two end notches **305** are illustrated, but varying numbers of end notches, or no end notches at all, are considered to be within the scope of the invention. The end notches **305** are raised slightly from the surface of the top lens **300**, and can be configured to be any one of notches, bumps, ridges, or indentations. The notches could also be of various shapes, sizes, and lengths. The top lens **300** is oriented so that, when the top lens **300** is inserted into the mid lens **200**, as discussed below, the raised projections or notches **305** face the mid lens **200** or may also project away from the mid lens **200**. The notches or projections **305** can provide directional and axial orientation for the top lens, similar to the axis orientation marks **85** of FIG. **5**.

The surgeon performing the operation or the lens manufacturer assembles the mid lens **200** and the top lens **300** outside the eye to a predetermined axis orientation to correct the astigmatism, and then inserts the completed assembly into the eye as one folded piece. A side view of the completed assembly of the top lens **300** and the mid lens **200** is illustrated in FIG. **16**. It is noted that in FIG. **16**, the angles and sizes have been exaggerated in order to illustrate the relationship between the top lens **300** and the mid lens **200**. It is also noted that, although in FIG. **16**, the side portion of top lens **300** is flush with the side region **250** of the mid lens **200**, and the bottom portion of top lens **300** is flush with the top portion of the mid lens **200**, this fitting is not required for the assembly of the top lens **300** and mid lens **200**. That is, embodiments in which the side portion of the top lens **300** is not flush with side region **250** of the mid lens are considered to be within the scope and pervue of the invention.

Once the base lens **100** has been inserted into and mounted within the eye, the surgeon inserts the top lens **300** and the mid lens **200** assembly into the base lens **100** by sliding a projection **210** into a slot **110** of a corresponding flange **105** of the base lens **100**. When attaching the assembly of the top lens **300** and the mid lens **200** to the base lens **100**, the surgeon does not need to visually see the individual pieces line up together. Instead, projection **210** is designed to slide into place with the slot **110**. That is, the surgeon unfolds the

assembly of the top lens **300** and the mid lens **200**, and then slides the assembly across the base lens **100** until a first projection **210** lines up with a first slot **110**. Once a projection **210** lines up with a slot **110**, the projection **210** catches in the slot **110**, and the surgeon will feel the two pieces lock into place. Once the first projection **210** is in place in the corresponding first slot **110**, if more projections are present in the mid lens **200**, then the surgeon adjusts the mid lens **200** and the top lens **300** until the other projection(s) **210** line up with the other slot(s) **105**. Once all projections **210** have been inserted into their corresponding slots **110**, the assembly of the top lens **300** and the mid lens **200** is secured in the base lens **100**, and the procedure is completed.

In the event that the assembly formed by the mid lens **200** and the top lens **300** requires replacement, the surgeon may perform a disassembly procedure as discussed herein. First, a cannula containing visco elastic material would be introduced into the eye and positioned at the interface between the lens assembly (mid lens **200** and top lens **300**) and the base lens **100**. The injection of visco elastic causes the mid **200**/top **300** lens assembly to elevate, thus disengaging the projections **210** from the slots **110** in the base lens **100**. The original lens assembly would then be removed from the eye, and a new lens assembly placed into the eye and attached to the base lens **100** similar to as described above in the primary operation.

While the invention has been described in conjunction with specific embodiments therefor, it is evident that various changes and modifications may be made, and the equivalents substituted for elements thereof without departing from the true scope of the invention. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from the scope thereof. Therefore, it is intended that this invention not be limited to the particular embodiment disclosed herein, but will include all embodiments within the spirit and scope of the disclosure.

For example, the mid lens **200** may also have additional spherical power ranging from −9.50 D to 9.50 D in 0.25 D increments, and may be either monofocal or multifocal. The top lens **200** may also be constructed from acrylic, silicone, or any other material suitable for crafting a foldable intraocular lens. The mid lens has a plano-convex lens with a central thickness ranging from 0.1 to 0.3 millimeters, and a diameter ranging from 1.5 to 8.5 millimeters, preferably between 6.0 and 6.5 millimeters, and an optical clear aperture ranging from 5.0 to 6.0 millimeters, preferably 5.5 mm. Similar to the base lens **100** and the top lens **300**, the mid lens **200** may also be manufactured in a manner to allow absorption of light in the ultraviolet wavelength portion of the light spectrum, or other portions of the light spectrum for which it may be clinically important to absorb light, such as the blue light portion.

Also, the mid lens **200** may have at least one bevel **210** formed along an outer edge thereof, allowing the mid lens **200** to fit into the opening **110** of the base lens **100**. The mid lens **200** has a projection/notch **225**, **230** that allows compression of the top lens **300** in order for the top lens **300** to fit inside the projection/notch **225**, **230** of the mid lens **200**. Prior to insertion into the eye, the surgeon or manufacturer places the top lens **300** into the mid lens **200**, and seals the top lens under the notch **225** around the entire circumference of the mid lens. The assembly is then ready for insertion into the eye of the patient.

The three piece system (i.e. the base lens **100**, the mid lens **200**, and the top lens **300**) described herein has a spherical power range of −20.00 D to +40.00 D and accuracy of +/−0.25 D. The three piece system has an adjustable cylindrical power of 5.00 D, and adjustable spherical power of +/−9.00 D. Its maximum central thickness is 1.88 millimeters, but could be as thick as 4.0 millimeters. The optical element diameter ranges from 1.00 millimeters to 8.00 millimeters. The optical aperture ranges from 3.0 to 7.0 millimeters, with an optimal optical aperture of 5.5 millimeters.

Any of the base, top, and/or mid lens components may be coated with chemicals to decrease their cellular reactivity, such as heparin or other surface passivation techniques to prevent building of cellular debris at the optical interface. Moreover, any of the lens components may be configured with a multifocal corrective component of any of several varieties: derefractive or refractive, bull's eye or aspheric, depending upon the desired optical characteristics. Additionally, extra components beyond the basic base, top, and mid components may be added to help with optical aberrations or other focusing refinements. In an embodiment of the present invention, additional top lenses may be added to the base lens **100**, and attached in the same manner as the assembly of the top **300** and the mid lens **200** described above.

In another embodiment of the present invention, a telescopic lens can be introduced into the lens system for the treatment of macular degeneration. If the base lens **105** illustrated in FIG. **13** is used, then the surgeon can cut the attachment points **140** while the lens is in the eye, and remove the central optic **150** of the base lens **105**. The surgeon can then implant a telescopic assembly, for example a Lipschitz telescopic assembly, in place of the optic portion of the base lens **105**, to allow optical correction for macular degeneration.

By using specific predetermined combinations of lens powers for each of the three components, it is possible to achieve a large variety of possible corrective power while requiring only a minimum number of different lenses to be manufactured. By placing small degrees of spherical construction in each of the three optical components, a surgeon can, from a very limited inventory of lenses, construct all of the corrections needed to achieve optical powers from −20.00 D to +40.00 D of spherical correction, and from 0.0 to 5.0 D of cylindrical correction in any axis, all in standard 0.25 D steps.

Optical aberrations and abnormalities present after implantation of the intraocular lens are identified by measuring the optical system using, for example, wave front technology. A surface modifier may be used to modify either a surface of the eye itself, or a component of the intraocular lens system. If a component requires modification or replacement, the surgeon can remove the component, alter the component or replace it with another, and reinsert the component through the same wound which was used to implant the lens. This process is described more fully in U.S. Pat. No. 6,413,276, "Modified Intraocular Lens and Method of Correcting Optical Aberrations Therein," by the same inventor.

What is claimed is:

1. A multi-component intraocular lens implantable in an optical system of a human eye, comprising:

a base lens having an anterior surface configured to face a front of the human eye, a posterior surface on an opposite side of the base lens relative to the anterior surface and configured to face a back of the human eye, a circumferential side surface connecting the anterior and posterior surfaces, and at least one projection extending away from the circumferential side surface and configured for securing the base lens within tissue of the human eye, the base lens being manufactured from a first foldable material and including at least one flange disposed on and extending orthogonally away from the anterior surface of the base lens toward the front of the

human eye, the at least one flange including an aperture defined therein, the aperture being located only above the anterior surface of the base lens; and

an optical assembly which selectively engages the anterior surface of the base lens, the optical assembly being manufactured from a second foldable material.

2. The intraocular lens of claim **1**, wherein the foldable optical assembly comprises:

at least one tab extending therefrom, the tab configured to engage the aperture of the at least one flange of the base lens.

3. The intraocular lens of claim **2**, wherein the tab is surface treated selected from the group of: notched, slotted, grooved, ridged, roughened, ribbed, gouged, striated, rifled, sulcated, corrugated, crimped, or canaliculated.

4. The intraocular lens of claim **1**, wherein the foldable optical assembly comprises:

a top lens; and

a mid lens that removably engages the top lens.

5. The intraocular lens of claim **4**, wherein the mid lens comprises an L-shaped lip extending upward and away from a planar surface of the top lens, wherein a notch is defined by the lip and the planar surface.

6. The intraocular lens of claim **5**, wherein the top lens is secured in the mid lens by the lip.

7. The intraocular lens of claim **5**, wherein at least one side of the lip is beveled.

8. The intraocular lens of claim **7**, wherein the notch engages at least an outer perimeter of the top lens.

9. The intraocular lens of claim **4**, wherein at least one tab extends from the mid lens, the at least one tab configured to engage the aperture defined in at least one flange extending from the base lens.

10. The intraocular lens of claim **4**, wherein the top or mid lens is constructed with a predetermined cylinder and diopter value for correcting astigmatism.

11. The intraocular lens of claim **4**, wherein the top or mid lens includes a coating capable of blocking or absorbing a specific light wavelength or range of wavelengths.

12. The intraocular lens of claim **4**, wherein the top or mid lens is configured to deliver a pharmaceutical compound into an inner portion of the human eye.

13. The intraocular lens of claim **4**, wherein the top or mid lens is provided with a coating which enhances the human eye's ability to see particular area of a light spectrum.

14. The intraocular lens of claim **4**, wherein the top lens is provided with a coating which enhances the human eye's ability to see at night.

15. The intraocular lens of claim **4**, wherein at least one of the mid lens and the top lens has at least one vision corrective component.

16. The intraocular lens of claim **1**, wherein the aperture has a shape selected from the group of: an ellipse, an oval, a trapezoid, a rounded rectangle, a parallelogram, a pentagon, hexagon, and an octagon.

17. The intraocular lens of claim **1**, wherein the base lens has at least one vision corrective component.

18. The intraocular lens of claim **1**, wherein the first foldable material is the same as the second foldable material.

19. The intraocular lens of claim **1**, wherein the first foldable material is different from the second foldable material.

20. The intraocular lens of claim **1**, wherein the base lens includes a removable optic portion defined by at least one breakable attachment point.

21. The intraocular lens of claim **20**, wherein the base lens further includes an annular housing joined to the removable optic portion by the at least one breakable attachment point.

22. The intraocular lens of claim **21**, wherein a telescopic lens assembly is inserted through the annular housing and retained therein by the at least one flange of the base lens in place of the removable optic portion once the removable optic portion is removed by cutting the at least one breakable attachment point.

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